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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,919	03/26/2004	Thomas Wisniewski	57953/1211 (2003-11-WIS02	9386

7590 04/26/2007

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,919	WISNIEWSKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 15-26* is/are pending in the application.

4a) Of the above claim(s) *21-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 March 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 4, 12 and 17 have been amended and claims 2-3 and 13-14 have been cancelled as requested in the amendment filed on March 13, 2007. Following the amendment, claims 1, 4-12 and 15-20 are pending in the instant application.

Claims 21-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 10, 2006.

Claims 1, 4-12 and 15-20 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on March 13, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 4-12 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating Alzheimer's disease by administration of a protein of SEQ ID NO: 4, does not reasonably provide enablement for the

full scope of the treatment and prevention of Alzheimer's by administration of an agent which inhibits interaction between amyloid-β peptide and apolipoprotein E. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

At p. 6 of the Response, Applicant submits that, "the present application provides an enabling disclosure for methods involving the administration of agents that inhibit interaction between amyloid-β and apolipoprotein E". Applicant further states that " "[p]rior studies identified residues 12-28 of amyloid-β as the binding site for apolipoprotein E binding to amyloid-β. Thus, synthetic peptide homologues to residues 12-28 of amyloid-β can be used as competitive agonists of the binding of full length amyloid-β to apolipoprotein E" (p. 7 of the Response). Applicant also relates to Example 5 as disclosing the competitive inhibition assay to identify agents that inhibit apoE/ amyloid-β interaction". Applicant's arguments have been fully considered but are not persuasive for the following reasons.

As fully explained in the previous communication of record, Applicant's invention is predicated on finding that administration of Aβ12-28P was beneficial with respect to reduction in amyloid plaque formation in transgenic mice and increase of cell viability in culture. The prior art discloses that Aβ12-28 binds to apolipoprotein E, which is also implicated in Alzheimer's pathology. Thus, based on the data obtained with Aβ12-28P, Applicant proposes a method of treatment of Alzheimer's disease by administration of an agent, which inhibits interaction between amyloid-β peptide and apolipoprotein E. This agent is not defined by similarity in structure to Aβ12-28P but is described as any agent that "inhibits interaction between amyloid-β peptide and apolipoprotein E"; such interaction appears to be limited to the binding between the

two molecules as explained in Example 5 (pp. 19-20 of the instant specification). One skilled in the art readily appreciates that half of the chemical compounds in existence would meet the limitation of an agent as presented in claims 1, 4 and 9-13 because any compound applied to the two molecules as described in protocol of Example 5, would either reduce or increase the binding between these molecules. The Examiner maintains that the instant claims 1, 4 and 9-13 are not enabling because they encompass an unreasonable amount of molecular embodiments while the specification is only limited to the disclosure of how to use one fragment of amyloid-β molecule with a specific substitution.

Applicant further argues that the instant specification is enabled for the method of prevention of Alzheimer's disease because the current point of view in the art is that "the amyloid cascade hypothesis has been the dominant organizing principle behind Alzheimer's research" (p. 8) and refers to the recent publication by Sadowski et al. "Blocking the Apolipoprotein E/ Amyloid-β interaction as a therapeutic approach for Alzheimer's disease" (p. 9). Applicant's arguments have been fully considered but are not persuasive because they do not relate to prevention of Alzheimer's disease, which encompasses administration of an agent, a modified fragment of amyloid-β, to general population as a prophylactic measure. The art clearly recognizes that etiology of Alzheimer's disease remains unknown; and the instant specification, as filed, fails to present any evidence or sound scientific reasoning to support a conclusion of beneficial effect of administration of an agent that inhibits interaction between amyloid-β peptide and ApoE. Applicant also fails to explain the relevance of information related to Alzheimer's pathology, such as the amyloid cascade hypothesis or "therapeutic approach for Alzheimer's disease", emphasis added, to preventive treatment of non-affected population.

Thus for reasons of record explained in the previous office communication and reasons set forth above, the instant rejection is maintained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6 and 17 stand indefinite for recitation of an agent that "has a three dimensional structure corresponding to the three dimensional structure of a protein" for reasons of record in section 12 of Paper mailed on Sept 13, 2006. The metes and bounds of the recitation cannot be determined from the claims or the instant specification. Clarification is required.

Conclusion

9. No claim is allowed.

10. This application contains claims 21-26 drawn to an invention nonelected with traverse in Paper filed on July 10, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

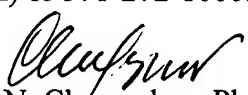
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

April 23, 2007